www.Sportronhealth.com

- One of the major active ingredients in CarboTone is Glucosol™….It has been used for centuries…for high blood-sugar control, to heal mouth ulcers…."
- "A clinical study…concluded, "the average blood glucose level dropped 31.9% with a 32 mg glucosol dose per day after 30 days."
- "Reported Benefits from Glucosol study: Lowering blood glucose levels in type 2 diabetics."
- "Another major active ingredient in CarboTone is Food Matrix Chromium…When Chromium is supplemented in the form of GTF and it is active in the human body, it will produce the following results: Controls blood glucose…, Reduces arteriosclerosis, increases resistance to infection.…"

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are also "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. Your products "Sportron's Diabetes FoodMatrix™ Pack" and "CarboTone" are also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for these drugs fail to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. While reviewing your web sites, we noticed that you promoted other products for disease treatment and/or prevention. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your websites, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be addressed to Kristen Moe, Compliance Officer, Food and Drug Administration, Division of Compliance and Enforcement, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

If you prefer to respond electronically, send your e-mail to kristen.moe1@FDA.HHS.GOV.
If you have any questions concerning this letter, please contact Ms. Moe at 301-436-2064.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition